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Response Under 37 CFR 1.116
Expedited Procedure
Examining Group 1647

STK-1 DIV-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants : John C. Lee and Lee-Chuan C. Yeh
Application No. : 09/287,500
Confirmation No. : 6377
Filed : April 7, 1999
For : COMPOSITIONS AND THERAPEUTIC METHODS
USING MORPHOGENIC PROTEINS AND
STIMULATORY FACTORS
Group Art : 1647
Examiner : D. Romeo

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D.G.
4/23/02
(NE)

New York, New York
April 9, 2002

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO OCTOBER 9, 2001 FINAL OFFICE ACTION

This responds to the October 9, 2001 Office Action. Applicants have petitioned concurrently herewith to extend the time for response to the Office Action for three months from January 9, 2002 up to and including April 9, 2002 and have paid the required fee under 37 C.F.R. 1.136(a) and 1.17(a)(3).

Applicants wish to thank the Examiner for granting applicants' undersigned agent a personal interview on January 25, 2002, discussing the October 9, 2001 Final Office Action. Applicants propose the following claim amendments, which were discussed during the 1/25/02 interview. It does not introduce any new matter, or raise any new issues that

would require further consideration or search. Applicants submit that the amendments place the claims into a condition for allowance, or at least present the rejected claims in better form for consideration on appeal and should therefore be entered after the final rejection under 37 C.F.R. § 1.116(a).

In the Claims:

Please amend the claims as follows¹.

Please delete claims 93, 94, 100 and 101 without prejudice.

Please amend claims 69, 74, 76 and 77 as indicated below.

69. (Three Times Amended) A method for inducing local tissue formation from a progenitor cell in a mammal comprising the step of implanting in the mammal a morphogenic device at a locus accessible to at least one progenitor cell of the mammal, whereby the morphogenic device induces local tissue formation from the progenitor cell in the mammal, the morphogenic device comprising:

- a) an implantable biocompatible carrier,
- b) a morphogenic protein disposed in the carrier, the morphogenic protein capable of inducing tissue formation when accessible to a progenitor cell, and
- c) a morphogenic protein stimulatory factor (MPSF) selected from the group consisting of hormones, cytokines, peptides and growth factors disposed in the carrier,

¹ An Appendix of Amendments is attached herewith showing the amendments. In the Appendix, additions are underscored and deletions are bracketed.

the stimulatory factor being at a concentration effective to synergistically stimulate the ability of the morphogenic protein to induce tissue formation from the progenitor cell,

wherein the MPSF is selected from the group consisting of IGF-I, hydrocortisone, insulin, and parathyroid hormone.

74. (Three Times Amended) A method of accelerating allograft repair and incorporation in a mammal, comprising the step of implanting at a locus in need of replacement bone a matrix-comprising device, whereby the device accelerates allograft repair and incorporation in the mammal, the device comprising:

- a) an implantable biocompatible carrier,
- b) a morphogenic protein disposed in the carrier, the morphogenic protein capable of inducing tissue formation when accessible to a progenitor cell, and
- c) a morphogenic protein stimulatory factor (MPSF) selected from the group consisting of hormones, cytokines, peptides and growth factors disposed in the carrier, the stimulatory factor being at a concentration effective to synergistically stimulate the ability of the morphogenic protein to induce tissue formation from the progenitor cell,

wherein the MPSF is selected from the group consisting of IGF-I, hydrocortisone, insulin, and parathyroid hormone.

76. (Three Times Amended) A method of promoting in vivo integration into a target tissue of a mammal an implantable prosthetic device, the method comprising the steps of:

- a) providing on a surface of the prosthetic device an osteogenic composition, and
- b) implanting the device in a mammal at a locus where the target tissue and the surface of the prosthetic device are maintained at least partially in contact for a time sufficient to permit enhanced tissue growth between the target tissue and the device,

wherein the osteogenic composition comprises (1) an morphogenic protein capable of inducing tissue formation when accessible to a progenitor cell, and (2) a morphogenic protein stimulatory factor (MPSF) at a concentration effective to synergistically stimulate the ability of the morphogenic protein to induce tissue formation from the progenitor cell, said morphogenic protein and MPSF disposed on the surface region in an amount sufficient to promote from a progenitor cell enhanced tissue growth between the target tissue and the device;

wherein the MPSF is selected from the group consisting of IGF-I, hydrocortisone, insulin, and parathyroid hormone.

77. (Three Times Amended) A method of treating a tissue degenerative condition in a mammal comprising the step of administering a pharmaceutical composition to